DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-14

April 24, 2001

Mr. Barton P . Buxton
Chief Operating Offficer
Crittenton Hospital
1101 West University
Rochester, MI 48307

Dear Mr. Buxton:

We are writing you because on April 18, 2001, your facility was inspected by a representative of the State of Michigan acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Repeat Level 2 finding at your facility:

1. Corrective action before further exams, for a failing phantom image score, or a background optical density, or density difference outside the allowable regulatory limits was not documented for the [redacted] mammography system in Room 1.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. This problems is identified as a Repeat Level 2 because it identifies a failure to meet a significant MQSA Requirement and indicates failure by your facility to implement permanent correction of problems found during your previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to placing your facility under a Directed Plan of Correction, charging your facility for the cost of onsite monitoring, assessing civil money

penalties up to $10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It addition, your response should also address the Repeat Level 3 finding that is also listed on the inspectional report provided at the close of the inspection. The Repeat Level 3 finding is:

1. The chest wall edge of the compression paddle is visible on the test image for the [redacted] mammography system in Room 1.

It is necessary for you to act on these matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Repeat Level 2 and Repeat Level 3 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures. if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to: Mr. David M. Kaszubski
Acting District Director
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

David M. Kaszubski

David M. Kaszubski
Acting District Director
Detroit District

Enclosures: a/s